

Drug Safety

Adverse drug reactions reported to a National HIV and Tuberculosis Health Care Worker Hotline in South Africa: description and prospective follow up of reports

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Electronic Supplementary Material 1. MIC Data Capture Forms: General queries and ADR follow-up.

Q#####

Name:		 Address/Facility:		Taken by:		Answer provided:			
 Tel:				Date:		1	Immediate	4	1 - 8 hrs
 Cell:				Time:		2	< 30 min	5	Next day
 Other:						3	30 min –1hr	6	2 - 5 days
Origin:		Region:		Profession:		Topic:		HIV/AIDS/TB Sub-Topics:	
1 Private Sector		01 W. Cape		01 GP/Specialist		01 ADR – other drugs		01 Adherence	
2 Public Sector		02 N. Cape		02 Pharmacist		02 Availability/Supply		02 ADR – ARV/TB drugs	
3 Groote Schuur		03 E. Cape		03 Intern/Student		03 Foreign Product ID		03 Dosage	
		04 Gauteng		04 Nurse		04 Tablet ID		04 Failure	
Contact method:		05 Mpumalanga		05 NIMART Nurse		05 Interaction		05 Initiating Therapy	
1 Telephone (default)		06 Limpopo		06 Medical Aid		06 HIV/AIDS/TB		06 Interactions	
2 E-mail		07 North West Prov		07 Industry		07 Lactation		07 IRIS	
3 SMS / PCM		08 Free State		08 Other HCW		08 Malaria		08 Lactation	
4 Other:		09 Kwazulu Natal		09 Lay Person		09 Medicolegal		09 Medicolegal	
		10 Other (outside)		10 Wholesaler		10 Other		10 Ols other than TB	
Demographics of the patient				11 Pharmaceutical		11 Other		11 Other	
*Age:		1	*Male	Y	Pregnant	12 Pharmacokinetics		12 Paediatrics	
Weight:		2	*Female	Gestation wks:		13 Pharmacology/MOA		13 PEP	
Clinical Scenario/Problem statement				14 Poisoning		14 Pharmacology		14 Pharmacology	
				15 Porphyria		15 PMTCT		15 PMTCT	
				16 Pregnancy		16 Poisoning/OD		16 Poisoning/OD	
				17 Psychopharmacology		17 Porphyria		17 Porphyria	
				18 Therapy		18 Pregnancy		18 Pregnancy	
						19 Resistance		19 Resistance	
						20 Second-line Regimen		20 Second-line Regimen	
						21 Switching Therapy		21 Switching Therapy	
						22 TB		22 TB	
						23 TDF Renal ADR		23 TDF Renal ADR	
						24 TDM		24 TDM	
						Reference sources:			
						01 AHFS			
						02 Briggs			
						03 BNF			
						04 Drugdex			
						05 Consultant			
						06 Industry			
						07 Internet:			
						08 Journal			
						09 Martindale			
						10 Medline			
						11 Meyler's SE			
						12 MIMS			
						13 NDOH guidelines			
						14 Package insert			
						15 SAMF			
						16 Stockley			
						17 Other:			
Question:									
						Y Clinical HIV Query			
Answer:						Reply			
						1	Oral – telephonic		
						2	Email / Fax		
						3	Literature supplied		
					Answer by		Peer reviewer		
					Date		Time		

HIV & CURRENT REGIMEN DETAILS:							
*Status 1 Negative 2 Positive 3 Unknown		Regimen 1 FDC (TDF+3TC/FTC+EFV) 6 AZT+3TC+LPV/r 4 ABC+3TC+EFV 5 ABC+3TC+LPV/r		Individual drugs (other regimens): 01 ABC 02 ATV 03 AZT 04 d4T 05 EFV 06 FTC 07 LPV/r 08 NVP 09 TDF 10 3TC 11 Other:		On co-trimoxazole? 1 Yes → 2 No 3 Unknown	
Treatment status 1 HAART (default) 2 PMTCT 3 PEP 4 Not on ARVs		Hepatitis B 1 Negative 2 Positive 3 Unknown				Date started: 	
				Disease markers CD4:		Date: 	
				VL:			
				*Regimen start date: 			
TB & CURRENT REGIMEN DETAILS:							
*Status 1 No TB 2 No TB – on prophylaxis 3 TB – on treatment 4 Unknown TB status		Diagnosed by: 1 Gene Xpert 2 AFB 3 Culture 4 Clinical 5 Unknown		Individual drugs (other regimens): 01 Amikacin 02 Capreomycin 03 Cycloserine 04 Ethambutol 05 Ethionamide 06 INH 07 Kanamycin 08 Levofloxacin 16 Other:		09 Moxifloxacin 10 Ofloxacin 11 PAS 12 PZA 13 RIF 14 Streptomycin 15 Terizidone	
Type of TB 1 P-TB 2 Extra P-TB 3 DR-TB 4 XDR-TB		Regimen 1 RHZE 2 RH 3 INH prop. 4 Not on TB meds				*Treatment start date: 	
# TB Episode:							
SUSPECTED ADR DETAILS:							
*Short description of suspected ADR:						*Date of onset of AE:	
Known allergies/ Previous similar reactions?						*Suspect drug(s):	
DRUG HISTORY (PAST MONTH) NOT INDICATED ABOVE							
Drug & dose (& route if not per os)		Date of first dose		Date of last dose		*Indication	
INVESTIGATIONS:		Date:	Date:	Date:	Date:	Date:	Date:
Relevant Labs							
ADR MANAGEMENT & FOLLOW-UP:							
*Plan for management (select <u>all</u> that apply) 1 Continue drug 2 Stop drug 3 Decrease dose 4 Substitute with: 5 Rechallenge 6 Monitor: 7 Gave information 8 Other:					*Current status of patient 1 Out-patient 2 In-patient 3 ICU patient 4 Other:		
We are following up on all patients with a suspected ADR. *When would be appropriate to follow-up?					Never		
*Reference for the call-back (E.g. folder number if state hospital, age, sex and initials if private sector)					None		

Query number		Date:
Updated status of patient 1 Out-patient 2 In-patient 3 ICU patient 4 Other:	Actions taken 1 Stopped drug 2 Substituted with _____ 3 Will rechallenge _____ 4 Decreased dose 5 Laboratory investigations done: _____ 6 Continued therapy 7 Antagonist given: _____ 8 Other treatment given: _____ 9 Discovered other possible cause: _____	Patient's condition... 1 Improved 2 Unchanged 3 Deteriorated 4 It's complicated: 5 Unknown
		Needs to be called again Yes No

Query number		Date:
Updated status of patient 1 Out-patient 2 In-patient 3 ICU patient 4 Other:	Actions taken 1 Stopped drug 2 Substituted with _____ 3 Will rechallenge _____ 4 Decreased dose 5 Laboratory investigations done: _____ 6 Continued therapy 7 Antagonist given: _____ 8 Other treatment given: _____ 9 Discovered other possible cause: _____	Patient's condition... 1 Improved 2 Unchanged 3 Deteriorated 4 It's complicated: 5 Unknown
		Needs to be called again Yes No